K052353

SEP - 9 2005

Pride Mobility Products Corp.

Research & Development
182 Susquehanna Ave
Exeter, PA 18643
570-655-5574
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Exhibit 1

510(k) Summary
Pride Mobility Products Corporation
Z-Chair Power Wheelchair

Submitter's Name & Address:
Pride Mobility Products Corporation
182 Susquehanna Avenue
Exeter, Pa. 18643
Phone: (570) 655-5574
Facsimile: (570) 655-2990

Contact Person:
Thomas Schappert
Official Correspondent

Date Prepared:
08-02-05

Name of Device and Proprietary Name:
Z-Chair / Pride Mobility

Common or Usual Name:
Powered Wheelchair Base Unit

Classification Name:
Physical Medicine / Wheelchair, Powered

Product Code:
ITI

Comparison to Predicate Devices:
The Z-Chair is substantially equivalent to the Pride Mobility Quantum Blast (K011993) when comparing configuration, maneuverability, stability, structure. The performance characteristics and the position of the drive mechanisms are similar to achieve the same intended use function that enables the user to maintain optimum stability without hindering performance. Both utilize rear-wheel drive technology with rear drive wheels, front casters, and rear anti-tip wheels. The key functional change between the Quantum Blast (K011993) and the Z-Chair is the Z-Chair's ability to disassemble into four pieces. The reason behind this is to make the product more portable for users who need to travel with the device. The device can essentially be taken apart and loaded into the trunk of a vehicle or stored in a compact space.

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Device Description:
The Z-Chair is a compact battery-operated power wheelchair featuring rear-wheel drive technology, front casters, rear anti-tip wheels, and a standard, programmable 50-amp Penny & Giles VSI controller. The Z-Chair is designed for, but not limited to Pride Mobility Products Corp. providers / retailers and their consumers.

As a motorized wheelchair, the Z-Chair offers 2 motors for operational purposes, electronic regenerative disc brakes, suspension, off-board battery charger, a fully programmable controller, and removable battery pack. Accessories include a lap belt, front basket, flag holder, cup holder, and zippered accessory pouch.

The Z-Chair is designed with ultimate safety, stability, performance, and portability in mind. The main feature of the Z-chair is that it can be disassembled into 4 parts: the rear section, the front section, the battery pack, and the seat. This allows for ease of use when traveling or storing the unit. The product also has a lightweight foldable seat, and a single-post, quick-release seat mount.

Intended Use:
The intended use of the Pride Mobility Products Corp. Z-Chair Powered Wheelchair is to provide mobility to persons limited to a seated position that have the capability of operating a powered wheelchair.

Non-Clinical Testing:
Compliance to applicable Testing Standards is as follows:
ANSI/RESNA WC/01 Determination of Static Stability
ANSI/RESNA WC/02 Determination of Dynamic Stability
ANSI/RESNA WC/03 Effectiveness of Brakes
ANSI/RESNA WC/05 Overall Dimensions, Mass & Turning Space
ANSI/RESNA WC/08 Test methods for Static, Impact and Fatigue Strengths
ANSI/RESNA WC/09 Climatic Tests
ANSI/RESNA WC/10 Obstacle Climbing
ANSI/RESNA WC/15 Documentation and Labeling
ANSI/RESNA WC Vol. 2-1998 Section 21 – Requirements and Test Methods for Electromagnetic Compatibility.
ANSI/RESNA WC/93 Maximum overall Dimensions
CAL 117 – Flammability Testing

Discussion of Clinical Testing Performed:
N/A

Conclusions:
The Z-Chair has the same intended use and similar technological characteristics as the Quantum Blast (K011993), moreover, the non-clinical testing and the predicate comparisons demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the Z-Chair is substantially equivalent to the predicate device (Blast). The Z-Chair has passed all the necessary testing procedures and is considered to be safe for user operation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 9 2005

Mr. Thomas Schappert
Official Correspondent
Pride Mobility Products Corporation
182 Susquehanna Avenue
Exeter, Pennsylvania 18643

Re: K052353
Trade/Device Name: Z-Chair - Powered Wheelchair
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered wheelchair
Regulatory Class: II
Product Code: ITI
Dated: August 19, 2005
Received: August 29, 2005

Dear Mr. Schappert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Mark N. Melkerson for
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit 3

Indications for Use

510(k) Number (if known): K

Device Name: Z-Chair - Powered Wheelchair

Indications for Use:

The intended use of the Pride Mobility Products Corporation Z-Chair Powered Wheelchair, is to provide mobility to persons limited to a seated position that have the capability of operating a Powered Wheelchair.

Prescription Use__X__ AND / OR Over-The-Counter Use__X__
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K052353